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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------------------|-----------------------------|
| 10/596,915 | 06/29/2006 | Raghupathi Kandarapu | GEN 3.3-008 | 2317 |
| 45776 7590 03/11/2010 DR. REDDY'S LABORATORIES, INC. 200 SOMERSET CORPORATE BLVD SEVENTH FLOOR BRIDGEWATER, NJ 08807-2862 | | | EXAMINER LOVE, TREVOR M | |
| | | | ART UNIT 1611 | PAPER NUMBER |
| | | | NOTIFICATION DATE 03/11/2010 | DELIVERY MODE ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patpros@drreddys.com

| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/596,915 | Applicant(s) KANDARAPU ET AL. | |
| | Examiner TREVOR M. LOVE | Art Unit 1611 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 February 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-8,12-18 and 21-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-8,12-18 and 21-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/19/2010 has been entered.

Claims 1, 4-8, 12-18, and 21-24 are pending.

Claims 2, 3, 9-11, 19, and 20 are cancelled.

Claims 1, 12, and 18 are currently amended.

Claims 21-24 are newly added. Note, claim 21 was proposed in an after-final amendment, however, said after-final amendment was not entered.

Claims 1, 4-8, 12-18, and 21-24 are currently under consideration.

Withdrawn Rejections and/or Objections

The objection to claims 9-11 for depending from cancelled claim 2 has been withdrawn in view of Applicant's cancellation of said claims.

The rejection of claims 1, 3-9, and 12-18 under 35 U.S.C. 102(b) as being anticipated by Close et al (European Patent number 0094116 (A2), published Nov. 16, 1983) has been withdrawn in view of Applicant's cancellation of claims 3 and 9, Applicant's amendments to claims 1, 12, and 18, and the new grounds of rejection set forth below.

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The rejection of claims 10-11 and 19-20 under 35 U.S.C. 103(a) as being unpatentable over Close et al (European Patent number 0094116 (A2), published Nov. 16, 1983) in view of Henriksen (U.S. Patent number 6,391,342, Patent published May 21, 2002) has been withdrawn in view of Applicant's cancellation of said claims.

New Grounds of Rejection

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

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not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 4-8, 12-18, and 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Close et al (European Patent number 0094116 (A2), published Nov. 16, 1983) in view of Lassen (U.S. Patent number 4,804,669).

Close teaches therapeutic, enteric coated granules which comprise a therapeutic active core wherein said core is coated by a first coating, which is subsequently coated with an enteric coating. Said first coating comprises a dispersing aid (see claim 1). Said dispersing aid is taught as being either an alkali metal phosphate or glycine (see claim 8), said glycine is water soluble. Said dispersing aid is present in an amount of approximately 0.5 to 7.5% (see claim 1), with a preferred embodiment being taught in example II being approximately 3.5% of the entire weight of the granules. The active core is taught as being selected from a plurality of active agents, all of which have some sensitivity to acid.

Close fails to directly teach that the active is an antidepressant, as newly required in amended claims 1, 12, 18, and 21. Close further fails to teach which specific antidepressant is present, as required in newly added claims 22-24.

Lassen teaches delivery of paroxetine to a human (see Abstract). Lassen teaches that paroxetine has "well-known anti-depressant effects" (see column 1, lines 34-40). Lassen further teaches that it can be useful to enterically coat paroxetine compositions (see column 2, lines 14-28).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the active of Lassen in the invention of Close. One would have been motivated to do so since Close is teaching a "superior time release therapeutic" which utilizes an enteric coating (see Close, Abstract), and Lassen is teaching a therapeutic that can be enterically coated. One would further have been motivated to utilize the coating method of Close since Close teaches a dispersing aid which "aid[s] in the dispersing of the enteric coating in the intestines" (see Close, page 5, lines 15-16).

Response to Arguments

Applicant argues in the remarks filed 02/19/2010 that Close does not mention antidepressant drugs, and that in view of the amendments to the claimed filed 02/19/2010 which require that the active comprise an antidepressant, the rejection under 35 U.S.C.102(b) over Close should be reconsidered. Applicant's argument is found persuasive, and therefore, the rejection under 35 U.S.C.102(b) over Close has been withdrawn. However, it is noted in the new grounds of rejection set forth above that while it is acknowledged that Close does not teach antidepressants, the teachings of Lassen cure said deficiencies.

It is noted that arguments directed to the combination of Close and Henriksen have not been addressed since, as Applicant properly identifies, "[t]hese claims are no longer pending, so the rejection is moot" (see Remarks, page 6, first paragraph).

Conclusion

No claims allowed. All claims rejected. No claims objected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TREVOR M. LOVE whose telephone number is (571)270-5259. The examiner can normally be reached on Monday-Thursday 7:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TL

/David J Blanchard/
Primary Examiner, Art Unit 1643

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